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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,981	08/29/2005	Lionel Vedrine	P-5753	5214
7590 David W Hightet Becton Dickinson and Company 1 Becton Drive-MC 110 Franklin Lakes, NJ 07417			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/520,981

Applicant(s)

VEDRINE, LIONEL

Examiner

BHISMA MEHTA

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28 2008 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the needle-supporting part comprising at least one secondary flange and the at least one secondary tab must be shown or the feature(s) canceled from the claim(s). It is unclear where these features are shown as the language used in the claims is not consistent with the language which is used in the specification for the description of the figures. No portion or component of the device has been defined as the needle-supporting part which therefore makes it difficult to ascertain where the needle-supporting part or the secondary flange are shown in the drawings. Furthermore, there is no portion or component of the device that has been defined as a secondary tab. It is suggested that the language of the specification and/or claims be amended such that the wording of the

claims corresponds to what is disclosed in the specification and shown in the figures.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Applicant has not explicitly stated in the specification what structure of the device performs the function recited with regards to

the spring means for moving the needle and the container to the retracted position. Applicant's remarks in lines 1-4 of page 7 have been noted but the disclosure of the spring means in lines 1-3 of page 3 has not been related to the spring which is disclosed in pages 4-7 of the specification. It is suggested that the specification be amended to specify that the spring means for moving the needle and the container to the retracted position is the spring. Appropriate correction is required.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the device as having a needle-supporting part comprising at least one secondary flange and as having at least one secondary tab able to engage with the secondary flange of the needle-supporting part. It is suggested that the language of the specification and/or claims be amended such that the wording of the claims corresponds to what is disclosed in the specification and shown in the figures. No new matter should be entered.

Claim Objections

5. Claims 5 and 7 are objected to because of the following informalities:

It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification. The specific means-plus-function being objected to is the spring means for moving the needle and the container to the retracted position of claim 5.

In line 1 of claim 7, it appears that the wording "as claimed in 6 claim 1," may be in error as it appears that the "6" has not been lined or crossed out.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the last line of claim 1, the use of "releasing it" is unclear as to whether "it" refers to the tab, the flange, or the plunger. Similarly, in line 10 of claim 7, the use of "unlock it" is unclear as to whether "it" refers to the secondary tab, the secondary flange, or the plunger. In the last portion of claim 1, the use of "said tab" is indefinite because it is unclear which of the at least one tab is being referred to. Similarly, in lines 5-8 and 10 of claim 7, the use of "said secondary flange" is indefinite because it is unclear which of the at least one secondary flange is being referred to and, similarly, the use of "this secondary tab" and "said secondary tab" is indefinite because it is unclear which of the at least one secondary tab is being referred to .

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (U.S. Patent No. 6,981,963) in view of Pfleger (U.S. Patent No. 4,929,230).

Barker et al disclose a device for injecting a product having a body (130) with a hollow injection needle (112) and a container (150) containing the injectable product. The device also has a plunger (120) that slides in the body. The container (150) is closed at one end and is connected to the plunger (120). Barker et al also disclose the device as including a piston (170) engaged in the container which is so shaped that, in a first configuration, closes the container and, in a second configuration, allows product to pass out of the container between itself and the container without the piston being pierced. The piston is spaced from, and not in contiguous contact with, the needle (112) with the piston being in the second configuration or position (Figure 16). The piston (170) in the second configuration as shown in Figures 14 and 15 allows the product to pass between the piston and the container. The device has a flange (200) formed at the opposite end of the container from the closed end and at least one tab (the distal part of 120 and shown adjacent 126 in Figure 12) which is able to move in the radial direction of the plunger between a radially inward position, in which the flange is connected to the plunger (Figure 12), and a radially outward position where the tab is withdrawn radially wide of the flange (Figure 13), thereby releasing the tab and the plunger. Barker et al also disclose the device as having spring means (126). The body

forms a distal end perpendicular to the axis of the needle, from which the needle projects.

Barker et al disclose the device substantially as claimed. However, Barker et al are silent on the specifics of the piston being so shaped to have a blind hole located adjacent a peripheral portion where the peripheral portion of the piston is deflected into the blind hole to allow the product to pass between the piston and the container. Pfleger disclose an injection device having a piston (33) engaged in a container (20) where the piston has a blind hole (48) located adjacent a peripheral portion (36) which is deflected to allow product to pass between the piston and the container and out of the container without the piston being pierced. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the piston of Barker et al with the piston having a blind hole located adjacent a peripheral portion as taught by Pfleger as Pfleger teaches that it is well known to use a piston with a blind hole and a peripheral portion that can be deflected to allow the flow of a product between the piston and the container. Since the use of the piston of Pfleger does not require and would not work with the fluid passage (160) of Barker et al, it would be obvious to one having ordinary skill at the time the invention was made that the substitution of the piston of Barker et al with the piston of Pfleger would not require and would not work with a fluid passage, and thus the device of Barker et al would be modified to not include this fluid passage.

Allowable Subject Matter

10. Claim 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 5-7 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's remarks in lines 5-10 of page 7, the incorporation of the subject matter of claim 8, which had previously been indicated allowable, into claim 1 does not render claim 1 allowable because the scope of claim 1 has been changed with the deletion of the means for holding the needle in position and the deletion of the respective means for operating said means of holding the needle in position and said means of holding the container.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761